SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. 5861–5900

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia), and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess; and Section 501(d)(2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502(e)(2), the article was a drug not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient including the quantity, kind, and proportion of alcohol contained therein; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use; and (2) adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling; Section 502(l), three articles were, or purported to be, or were represented as, drugs composed partly of penicillin, and another article was represented as a drug composed partly of chlorotetracycline, and none of the articles were from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

DRUGS FOR HUMAN USE

5861. Private Formula tablets. (F.D.C. No. 42858. S. No. 6–059 P.)

QUANTITY: 51,000 tablets in bulk container at Washington, D.C.

SHIPPED: 1–22–59, from Philadelphia, Pa., by Hance Bros. & White Co.

LABEL IN PART: "Private Formula * * * Each containing: d-1 Desoxyephedrine HCL 37½ mg. Phenobarbital ⅝ Gr. Warning * * * Aloin ⅝ Gr. Dose: One tablet daily or as directed by physician. Hance Bros & White Co., * * * Philadelphia."

LIBELED: 2–26–59, Dist. Columbia.

CHARGE: 502(j)—when shipped, the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling.

DISPOSITION: 5–21–59. Default—destruction.

5862. Barnes-Hind Wetting Solution. (F.D.C. No. 43134. S. No. 62–351 P.)

QUANTITY: 21 doz., 2-oz. plastic btls. at Chicago, Ill.

SHIPPED: 2–19–59, from Sunnyvale, Calif., by Barnes-Hind Ophthalmic Products, Inc.

LABEL IN PART: (Plastic btl.) "Barnes-Hind Wetting Solution. An antiseptic wetting-out cleansing and sanitizing solution to be used with plastic contact lenses. * * * Active Ingredients: Benzalkonium chloride 0.002% * * * Barnes-Hind Ophthalmic Products, Inc., 895 Kifer Road, Sunnyvale, Calif."

RESULTS OF INVESTIGATION: Examination of the article showed that it was not sterile but was contaminated with viable micro-organisms of the Pseudomonas group.

LIBELED: 5–1–59, N. Dist. Ill.; amended 5–5–59.

CHARGE: 501(c)—when shipped, the purity or quality of the article fell below that which it purported or was represented to possess, since it was represented as suitable for use in the eye, whereas it was not suitable for such use by reason of contamination with Pseudomonas; and 502(j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions: Gently rub 2 or 3 drops of Barnes-Hind Wetting Solution over the entire inner and outer surfaces of the lenses. Do not dry lenses before inserting."

DISPOSITION: 7–27–59. Default—destruction.

DRUG FOR VETERINARY USE

5863. Crisp Tonic Pills (veterinary). (F.D.C. No. 43170. S. No. 56–425 P.)

QUANTITY: 1 drum containing 4,500 tablets and 17 30-tablet boxes at Blacksburg, S.C., in possession of S. A. Crisp Canine Co.

SHIPPED: 8–30–47, from Passaic, N.J., by Purity Drug Co.

LABEL IN PART: (Drum) "Special Formula * * * pills S. C. Brown Each Pill Contains: Strychnine Sulfate 1/120 gr. Arsenic Trioxide 1/60 gr. Reduced Iron 1 gr. Extract Gentian 1 gr. Caution * * * Purity Drug Co. Inc., New York, N.Y. Passaic, N.J. 6603"; (box) "Crisp's Tonic Pills for Dogs * * * Each Containing Reduced Iron 1 gr. Strychnine Sulphate 1/120 gr. Arsenic Trioxide 1/16 gr. Extract Gentian Q.S. Directions * * * S. A. Crisp Canine Co., Blacksburg, S.C."

ACCOMPANYING LABELING: Pamphlets entitled "Crisp Canine Remedies."

RESULTS OF INVESTIGATION: The tablets in the boxes were shipped in bulk as described above and then were repacked and relabeled by the S. A. Crisp Canine Co. Analysis showed that the article contained about four times the declared amount of strychnine sulfate per tablet.

The pamphlets were prepared locally for the dealer.

LIBELED: 6–22–59, W. Dist. S.C.